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SPECIAL STATUS APPLICATION

Appl. No. 10/659,413
Reply to Final Office Action mailed April 12, 2005
Amendment and Reply AF dated May 19, 2005

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. This Amendment and Reply to the final Office Action mailed April 12, 2005 is being filed within the 3-month shortened statutory period. Applicants note that this application has been granted ***Special Status*** and respectfully request that the Examiner expedite her review of this Amendment and Reply.

Independent claim 32 has been amended to delete language that was deemed to be indefinite and to add language specifying that the antiseptic composition is packaged in a sterile and pyrogen-free form. This subject matter was previously recited in claim 44, which was dependent on claim 32. Claim 44 has consequently been amended to remove the dependency on claim 32.

Claim 40 has been amended to substitute the term "active substance" for the term "agent," which was deemed indefinite. The term "active substance" is recited in applicants' specification, for example, at page 15, lines 14 and 27 in connection with the subject matter of claim 40.

Independent claim 54 has been cancelled for purposes of expediting the allowance of the other pending claims and without prejudice to applicants' ability to present this claim or similar claims in the future. The dependency of dependent claims 34, 37, 39, 40, 42, 44, 46 and 47 has consequently been amended to delete reference to claim 54.

Independent claim 55 has been amended to specify that the solvent comprises saline. This subject matter was previously recited in claim 39, which was dependent on claim 55. Claim 39 consequently has been amended to remove the dependency on claim 55.

Independent claim 56 has been amended to delete reference to the lock flush composition being "safe," which was deemed to be indefinite, and to specify that the lock flush composition is sterile and pyrogen-free. This subject matter is recited in claim 44, which was previously dependent on claim 56. Claim 44 has consequently been amended to remove the dependency on claim 56.

Claims 32, 34, 37, 39-42, 44-47, 55 and 56 are pending, with claims 32, 55 and 56 being in independent claim format. The claim amendments presented above do not introduce any new, previously unclaimed subject matter and, applicants urge, are appropriate after final rejection.

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The amendment after final rejection, applicants submit, places the claims in condition for allowance. If the Examiner deems that the claims are not in allowable condition, applicants' request entry of the above amendments to place the claims in better form for consideration on appeal.

Claim Objections

The Examiner objected to Claim 56 because the term "in" in line 5 of the claim is used twice. This is not in error. The term "in-dwelling access catheters" is a term of art that means access catheters that are permanently or semi-permanently installed in a patient. Applicants' claimed lock flush compositions are biocompatible for use in such (in-dwelling) permanently or semi-permanently installed devices. Applicants submit that correction is not required.

The Examiner also objected that claims 34, 37, 39, 40, 42, 44, 45, 46 and 47 depend on higher-numbered claims such as 54, 55 and 56. This is necessary since newly added claims must be numbered consecutively from the previously added and considered claims. Prior to issuance, the claims will be renumbered. Applicants submit that correction is not required.

Claim Rejections – 35 USC §112

The word "safe" in claims 32 and 56 was deemed vague and subjective. Claims 32 and 56, and the claims dependent thereon, were consequently rejected for failing to particularly point out and distinctly claim the subject matter of applicants' invention. Applicants do not acquiesce in this rejection but, for purposes of expediting prosecution and allowance of the pending claims, have eliminated the word "safe" from claims 32 and 56.

The word "modest" in claim 32 was deemed to be a relative term that rendered the claim indefinite. Claims 32 and the claims dependent thereon were consequently rejected for failing to particularly point out and distinctly claim the subject matter of applicants' invention. Applicants do not acquiesce in this rejection but, for purposes of expediting prosecution and allowance of the pending claims, have eliminated the word "modest" from claim 32.

Claim 40 was rejected on the basis of its use of the term "substantially" and for its use of the term "agent." The term "agent" has been replaced with the term "active substance," which is used in the specification at page 15, lines 14 and 27. Non-limiting examples of active

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substances, such as other antimicrobial or biocidal components, proteolytic agents, and the like that don't deleteriously affect the activity and/or stability of the EDTA salt(s) are cited in applicants' specification, for example, at the paragraph spanning pages 15 and 16. Applicants submit that the term "active substance" is definite as it is used in applicants' pending claims.

The term "substantially" is used in claim 40 in the context of the claimed composition being "substantially free from an active substance other than an EDTA salt(s)" having a specified level of anti-microbial and/or antifungal activity. A cursory survey of the Delphion U.S. Patent database indicates that the terminology "substantially free from" is used in the claims of 3,313 issued U.S. patents in the Delphion database in a wide range of technology areas. A small sample of issued U.S. Patents having claims and specifications incorporating the terminology "substantially free from" is presented in tabular form in Exhibit A. Exhibit A references the specific claims that use "substantially free from" language and references where the language is used in the specification. Copies of these U.S. Patents will be provided to the Examiner promptly upon her request.

It is clear from the patents cited in Exhibit A that the terminology "substantially free from" is considered to be definite with respect to a broad range of subject matter without requiring explanation or further definition in the specification. Applicants submit that one having ordinary skill in the art of antiseptic compositions and lock flush compositions would know and understand what is encompassed by the claimed antiseptic composition being "substantially free from" other active substances having substantial antimicrobial and/or anti-fungal activity. Substantial antimicrobial and/or anti-fungal activity, in this context, means anti-microbial and/or antifungal activity that is at least 50% of the anti-microbial and/or antifungal activity of a sodium EDTA salt(s) composition in aqueous solution at a concentration of 4.0% (w.v) at a pH of 10.5

Applicants submit that the pending claims particularly point out and distinctly claim the subject matter of applicants' invention and fully satisfy the requirements of 35 U.S.C. §112.

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Claim Rejections – 35 U.S.C. §102(b)– Kurginski and 35 U.S.C. §103

Claims 32, 34, 37, 40-42, 45 and 54-56 were finally rejected under 35 U.S.C. §102(b) as being anticipated by *Kurginski* (GB 1 279 148). Applicants specifically do not acquiesce in this prior art rejection and have presented amended claims to expedite prosecution and allowance of claims rather than to correct deficiencies in the previously pending claims.

Applicants' independent claims 32, 55 and 56 have been amended to introduce additional subject matter or to provide clarification and thereby remove *Kurginski* from consideration as a 102(b) anticipating reference. Specifically, the Examiner notes that *Kurginski* fails to recite: (i) a saline carrier for the EDTA injection; (ii) employment of the composition in a sterile, pyrogen-free form; and (iii) employment of the composition in a sterile condition in a prefilled syringe.

Based on the Examiner's outstanding rejections, independent claims 32 and 56, amended to incorporate subject matter from claim 44, would be subject to the obviousness rejection of claim 44 – that is, independent claims 32 and 56 would allegedly be obvious in view of *Kurginski* and *Remington's Pharmaceutical Sciences*. Based on the Examiner's outstanding rejections, independent claim 55, amended to incorporate subject matter from claim 39, would be subject to the obviousness rejection of claim 39 – that is, claim 55 would allegedly be obvious in view of *Kurginski* and *Remington's Pharmaceutical Sciences*. These rejections are respectfully traversed.

Kurginski discloses an industrial cleaning solution for use in the sanitary maintenance of toilet facilities. Applicants disagree with the Examiner's characterization of *Kurginski*, in that she alleges it teaches a method for cleaning soils that accumulate in toilets and sanitary facilities ***due to*** bacterial and fungal growth by applying a cleaning composition to the surface. The *Kurginski* invention relates to a cleaning composition useful for releasing the particular soils that tend to accumulate in toilets and similar sanitary facilities. (*See*, page 1, lines 12-15.) Three types of "soils" are problematic in the management of sanitary facilities and are targeted for cleaning by the *Kurginski* composition: (1) mineral-like deposits that accumulate on and adhere to toilet surfaces (*See*, page 1, lines 22-48); (2) closely adherent fecal matter (*See*, page 1, lines 49-57); and (3) rust (*See*, page 1, lines 58-62).

These soils *may provide a site for* bacterial and fungal growth (*See*, page 1, lines 60-62.) and the growth of the microorganisms over a period of several weeks, may constitute another soil

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problem. Applicants submit, however, that *Kurginski* is *not* directed to and would not be perceived by one of ordinary skill in the art as teaching the removal or reduction of microbial growth *per se*. Applicants do not perceive any teaching or suggestion, in *Kurginski*, that *Kurginski*'s composition would function, or is intended to function, to reduce or eliminate microbial populations, other than incidentally as a result of the removal of the other soils which may provide a site for growth of microbial and fungal populations. In fact, *Kurginski* teaches that, when desired, a germicide can be added to a composition of the invention to disinfect or sterilize surfaces (*See*, page 3, lines 74-76). This teaching would suggest that the *Kurginski* composition does *not* have a germicidal or bactericidal effect and one of ordinary skill in the art would *not* look to the compositions of *Kurginski* to provide a bactericidal effect in any application or setting.

Remington's Pharmaceutical Sciences discloses that syringes are instruments intended for injection of liquids into the body or its cavities and describes different types of syringes. Applicants agree that hypodermic syringes are well known and that pyrogen-free solutions and saline solutions are conventionally used for compositions intended for human or animal therapeutic or diagnostic injection.

Applicants submit that *Kurginski* and *Remington's Pharmaceutical Sciences* are ***not*** properly combinable under 35 U.S.C. §103 because they are non-analogous prior art references. The Examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. MPEP §2141.01(a). If the general scope of a reference is outside the pertinent field of endeavor, the reference may be considered analogous art if subject matter disclosed therein is relevant to the particular problem with which the inventor is involved. *Id.* And, a prior art reference must be considered in its entirety, i.e, as a whole, including portions that would lead away from the claimed invention. MPEP 2141.02.

As discussed above, *Kurginski* teaches a composition that is useful for the removal of the hard, stone-like deposits resulting from urine, for the removal of securely adherent and perhaps dried fecal matter, and for the control of accumulation of rust in toilets and similar sanitary facilities. *Remington Pharmaceutical Sciences* discloses general information relating to hypodermic equipment, such as syringes that are used to administer medication subcutaneously, intradermally, intravenously or intramuscularly.

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Remington Pharmaceutical Sciences is relevant to the particular problem with which the applicants are involved, to the extent that applicants' antiseptic compositions may be administered using prefilled syringes. *Kurginski,* however, is wholly outside the field of applicants' endeavor. *Kurginski* is not directed to preventing, reducing and/or eliminating bacterial infection; rather, it is directed to removing hard and securely adherent material from toilets. Combination of the *Kurginski* and *Remington Pharmaceutical Sciences* references is improper because they are non-analogous prior art.

If the combination of *Kurginski* with *Remington Pharmaceutical Sciences* is deemed proper, applicants submit that the Examiner has not and cannot establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *Id.* Applicants submit that the Examiner has not established a *prima facie* case of obviousness.

The Examiner argues that it would have been obvious to a person of ordinary skill in the art to be motivated to employ the claimed compositions without pyrogens, and with a carrier such as saline solutions *as is conventional with therapeutic regimen,* and with conventional sterile protocols. Had a person of ordinary skill in the art known that the claimed compositions were useful in conventional therapeutic or diagnostic regimens, applicants may agree with the Examiner. Absent applicants' discovery and teachings, however, no one would have known that the claimed compositions were useful for any therapeutic or diagnostic regimen. One of ordinary skill in the art would certainly *not* have been led or motivated to prepare or use the claimed compositions in a conventional sterile therapeutic or diagnostic manner by any teachings of *Kurginski.* There is no suggestion in either *Kurginski* or *Remington Pharmaceutical Sciences* for any such combination, nor would there be any expectation of success in view of the prior art references cited.

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In particular, applicants submit that *no one* would have been motivated to use the toilet cleaning compositions of *Kurginski* in a sterile, pyrogen-free form or with a carrier such as saline or packaged in a sterile single-use vial or a prefilled syringe. Certainly one would ***not*** be motivated to use the use the toilet cleaning compositions of *Kurginski* in a sterile, pyrogen-free form, or with a carrier such as saline, or packaged in a sterile single-use vial or a prefilled syringe, for purposes of removing hardened deposits from toilet surfaces. Furthermore, applicants do not perceive, based on the teachings of *Kurginski* and *Remington's Pharmaceutical Sciences*, that one would be motivated to use the toilet cleaning compositions of *Kurginski* in a sterile, pyrogen-free form, or with a carrier such as saline, or packaged in a sterile single-use vial or a prefilled syringe for any other purpose. Considering *Kurginski* and *Remington's Pharmaceutical Sciences* in their entireties, one would certainly ***not*** be motivated to use the toilet cleaning compositions of *Kurginski* in a sterile, pyrogen-free form, or with a carrier such as saline, or packaged in a sterile single-use vial or a prefilled syringe for any human health purpose, such as lock flushing in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

Conclusion

Applicants urge that the claims, as amended, are in allowable form. Early reconsideration and allowance of applicants' pending claims is respectfully requested. If the Examiner deems the pending claims *not* to be allowable, applicants' representative respectfully requests a telephone interview prior to the Appeal deadline to discuss any outstanding issues.

Respectfully submitted,

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Date: May 19, 2005

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EXHIBIT A

U.S. Patent No.	Title	Issue Date	Terminology Used	Claims	Specification Reference(s) [Column & Line No.]
6,387,352B1	Mouthwash Composition	05.14.02	*"substantially free from CO_2, etc."*	1, 13, 20, 32, 33	Col. 6, line 29
			"substantially free from phosphate ions"	3	
			"substantially free from calcium ions"	3	
			"substantially free from fluoride ions"	37	
			"substantially free from zinc ions"	38	
			"substantially free from any other ingredient..."	48, 52, 58, 59, 60	Col. 6, line 39
6,712,121B2	Antimicrobially-Treated Fabrics	03.30.04	*"substantially free from said antimicrobial agent"*	3, 11, 27, 31	Col. 2, line 54
			"substantially free from any residual antimicrobial agent"		Col. 5, line 42
6,602,997B2	Whole Cell and Cell-Debris Polysaccharide	08.05.03	*"substantially free from whole bacterial cells and bacterial cell debris..."*	1-5	Col. 2, line 40 Col. 3, line 58 Col. 4, line 57 Col. 5, line 30 Col. 6, line 9 Col. 6, line 27
6,576,213B1	Method of Producing Chlorine Dioxide	06.10.03	*"substantially free from tin or tin compounds"*	1-5, 9	Col. 2, line 53
6,548,084B2	Controlled Release Compositions	04.15.03	*"substantially free from polalkenyl polyether"*	3, 4, 7, 8, 11	Col. 2, line 14
6,485,763B1	Shelf-Stable, Spreadable Maple Syrup Compositions	11.26.02	*"substantially free from crystallization"*	15-24	Col. 4, line 7
6,326,435B1	Polyester Resin Composition	12.04.01	*"substantially free from a bisoxazoline compound"*	1, 20, 21, 24, 25	Col. 3, line 24
5,969,093	Secreted Proteins	10.19.99	*"substantially free from other mammalian proteins"*	2, 6, 10, 14	Col. 3, line 51

4,985,153	Method for Separating Blood into Blood Components, and Blood Components Separator Unit	01.15.91	*"substantially free from leukocytes"*	8, 11, 13, 17, 21	Col. 8, line 26
			"substantially free from leukocytes and platelets"	8, 12, 13, 17, 21	Col. 8, line 29
4,132,780	Azide-Metal Salt Formulations for Control of Fungi and Nematodes	01.02.79	*"substantially free from substances which decompose the azide"*	1, 9, 36, 44	Col. 5, line 50
			"substantially free from substances causing/which cause decomposition of the azide"	18, 20, 25, 35, 53, 58, 68	Col. 14, line 64
			"substantially free from angular surfaces"		Col. 15, line 7

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